Baseline Characteristics and Adherence Among Multiple Sclerosis Patients Initiating Siponimod in Real World

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Background

- Multiple sclerosis is a chronic, inflammatory disorder of central nervous system damaging the neurons, with associated neurologic symptoms and disability dependent on the disease phenotype like relapse–remitting or secondary progressive disease.[1]
- Adherence to medication in MS is still a challenging requirement with high variability among patients due to the chronic nature of disease and long treatment duration.[2]
- Lower adherence is associated with negative clinical and economic outcomes like increased relapses, disease progression, hospitalizations, absence from work and higher medical costs.[3,4,5] Previous studies have indicated a level of adherence above 80% as optimal because adherence at this level significantly reduces the risk of hospitalization, acute medical visits and total expenditures for MS management.[6]
- Siponimod (Mayzent)® is a new–generation sphingosine–1 phosphate (S1P) receptor modulator administered orally once–a day, studied in secondary progressive multiple sclerosis (SPMS) patients in pivotal RCT EXPAND Trial.[7]
- It was approved by US FDA on March 26, 2019 for the treatment of adults with relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease (SPMS).[8]
- This is the first look at adherence in MS patients newly initiating once-daily, oral siponimod using longitudinal patient-level claims data from March 2019 to September 2020.

Objectives

- The aim of the present study was to assess the baseline demographic, clinical, treatment characteristics, and adherence in new siponimod initiator MS patients.

Methods

- This retrospective observational cohort study used Marketscan Commercial and Medicare Supplemental claims databases in MS patients who were initiated on Siponimod during March 2019–September 2020.

Inclusion criteria

- Adults (≥18 years) with MS diagnosis (ICD-9 Code: 340; ICD-10 Code: G35) in 12 months prior to index date defined as first observed claim for siponimod, who had ≥1 claim for siponimod in the index period (March 2019–September 2020) and were continuously enrolled in pharmacy and medical benefits for 12 months prior and with at least 6 months follow–up post–index date were included in the study.
- Patients with 12 months of continuous enrollment post–index were included and assessed as a subgroup in the study.
- Patients were classified based on their follow up duration of ≥6 months or ≥12 months post index and further based on their claim for prior disease modifying therapy (DMT), were classified as Naive (No DMTs during the 12–month baseline period) or switch population (Had ≥1 DMTs during the 12–month baseline period).

Study outcomes

- Patient demographic details including age on index, gender, geographical region, health plan type or insurance plan type; Clinical characteristics including Charlson comorbidity index (CCI), MS disability, MS relapses, other comorbidities and adherence (as defined as proportion of days covered [PDC]) data were analyzed.
- MS disability levels[9]: patients with mild disability had severity level 1 impairment of only one functional system, with moderate disability had severity level 1 impairment of more than one functional system or had any severity level 2 EDSS–related symptoms and with severe disability had any severity level 3 EDSS related symptoms.
- MS relapses was defined as published previously by Chastek and colleagues[10] (defined as those with MS diagnosis claim at any time during an inpatient hospitalization or those with MS diagnosis in an outpatient setting in addition to a pharmacy or medical claim for a qualifying corticosteroid on the day of or within 7 days after the visit).
- PDC was calculated as the number of days in follow–up period that the patient had siponimod on hand, divided by the total number of days in the follow–up period.
- Results were reported for patients with at least 6 months and 12 months follow up period from index date. Some patients from ≥6 months follow up cohort were also followed up to ≥12 months and were included in ≥12 months follow up cohort.

Results

- Overall, 143 and 34 MS patients initiating siponimod in real world were followed–up for ≥6–month and ≥12–month, respectively.

Baseline demographic characteristics

- The mean age of the patients was 52.3 years in the ≥6–month cohort and 55.2 years in the ≥12–month cohort. Overall, 67% patients in both cohorts were in 45-64 years of age.
- The majority of patients were females (≥70%) and other key patient demographics are summarized in **Table 1**.

Table 1: Patient demographics

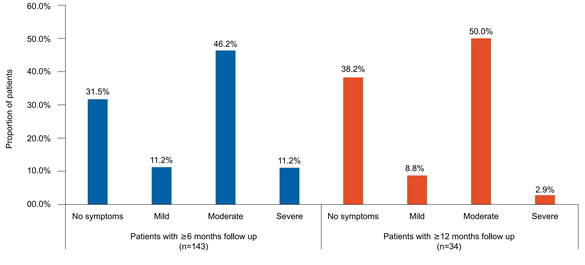
Baseline Demographic Characteristics	Patients with ≥6 months follow up (n=143)	Patients with ≥12 months follow up (n=34)
Age (years), mean (SD)	52.3 (10.3)	55.2 (10.1)
Age group (years), n (%)		
18–34	6 (4.2%)	0 (0%)
35–44	27 (18.9%)	5 (14.7%)
45–54	48 (33.6%)	12 (35.3%)
55–64	48 (33.6%)	11 (32.4%)
65+	14 (9.8%)	6 (17.6%)
Female, n (%)	103 (72.0%)	26 (76.5%)
Male, n (%)	40 (28.0%)	8 (23.5%)
Geographic Region, n (%)		
Northeast	41 (28.7%)	12 (35.3%)
North Central	29 (20.3%)	9 (26.5%)
South	56 (39.2%)	9 (26.5%)
West	16 (11.2%)	4 (11.8%)
Unknown	1 (0.7%)	0 (0%)
Insurance plan type, n (%)		
Commercial	128 (89.5%)	28 (82.4%)
Medicare Supplemental	15 (10.5)	6 (17.6%)
Health plan type, n (%)		
Fee for service	122 (85.3%)	32 (94.1%)
HMO and POS capitation	18 (12.6%)	2 (5.9%)
Unknown	3 (2.1%)	0 (0%)

HMO: Health maintenance organizations POS: Point of service plan; SD: Standard deviation.

Baseline Clinical Characteristics

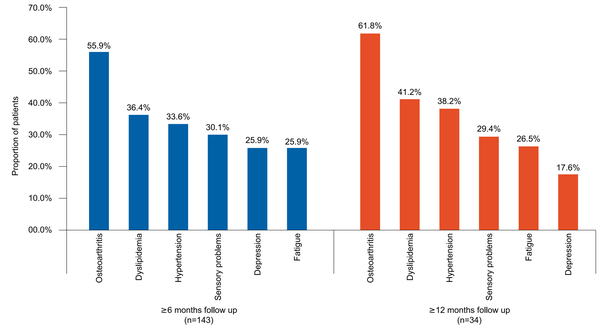
- Between 53-57% of the patients had moderate to severe disability level, as defined by symptoms in the claims while around ≥30% of patients had no disability at baseline **(Figure 1)**.

Figure 1: MS disability level at baseline



- At baseline most of the patients had no relapse (58.7% and 70.6% patients, in ≥6–month and ≥12 months follow–up cohort, respectively).
- Most commonly observed comorbidities at baseline were osteoarthritis, dyslipidemia, hypertension, sensory problems, fatigue and depression **(Figure 2)**. The mean CCI score at baseline was 0.66 (1.06) for ≥6–month follow up cohort and 0.47 (0.86) for ≥12–month follow up cohort.
- At baseline, 25.9% patients in ≥6–month follow up cohort and 23.5% patients in ≥12–month follow–up cohort had reported at least 1 relapse, while 15.4% patients in ≥6–month follow up cohort and 5.9% patients in ≥12–month follow–up cohort, had 2+ MS relapses.

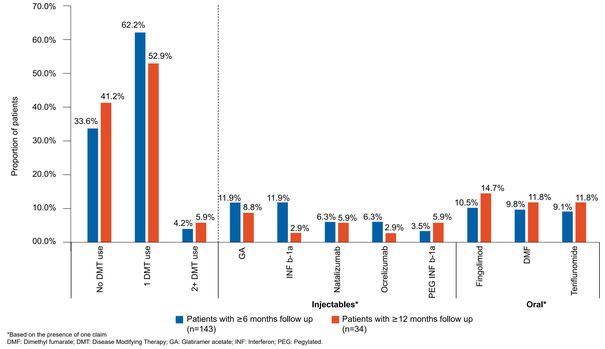
Figure 2: Major comorbidities experienced by patients



Baseline Treatment Characteristics

- Among patients newly initiating siponimod in the real world, around 33% of the patients had no prior DMT usage, while around 62% of the patients had prior exposure to 1 DMT, data for prior treatment is presented in **Figure 3**. Furthermore, switch patients were slightly older with 35.8% patients compared to 29.2% naive patients belonging to 45–54 years age group.

Figure 3: Prior DMT usage at baseline



*Based on the presence of one claim
DMF: Dimethyl fumarate; DMT: Disease Modifying Therapy; GA: Glatiramer acetate; INF: Interferon; PEG: Pegylated.

Treatment adherence

- MS patients while on siponimod treatment showed PDC ≥0.8 among 81.1% patients of ≥6-month follow up and in 82.4% patients of ≥12-month follow up cohort. Overall mean adherence of 0.84 was observed in patients of ≥6-month follow up cohort, along with 0.83 and 0.85 mean adherence in DMT naive and switch patients of the same cohort. Similar, adherence pattern was observed in ≥12-month follow up cohort, data presented in **Table 2**.

Table 2: Mean adherence data

Cohort	Naive	Switcher	Overall
≥6 months follow-up	0.83 (0.23)	0.85 (0.21)	0.84 (0.22)
≥12 months follow-up	0.79 (0.33)	0.82 (0.31)	0.81 (0.31)

Data reported as mean (sd) values

Limitations

- Patient coverage limited to commercial or private Medicare supplemental might have resulted in lack of generalizability of results.
- Chances of misclassification of patients due to coding errors or omissions resulting from administrative claims data during patient identification and selection.
- Claims data indicate only the receipt of medication rather than its usage by the patient and also relatively lesser number of patients were followed for ≥12 months.
- This study was the first real world account of adherence among siponimod initiators, however, study with larger sample and longer follow up are needed for future research.

Conclusion

- Early real–world claims data suggest favorable adherence (mean PDC ≥0.8) among siponimod users over at least 6 months of follow up with most reporting stable relapse status over the same period.
- Understanding patient profile and adherence in real–world setting may guide treatment decisions in clinical practice.

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Disclosures

- **Chinmay Deshpande, Fei Yang, Wing Chow, Gina Mavrikis Cox** are employees of Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA
- **Mengru Wang and Yutong Chang** are employees of KMK Consulting, Inc., Morristown, NJ, USA
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